William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Attorneys for Novartis Pharmaceuticals Corporation

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. AKORN, INC.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; and USV NORTH AMERICA, INC., Defendants.	)	Civil Action No. 13-XXXX (XXX) (XXX)

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendants' requests for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Zometa® and Reclast® prior to the expiration of U.S. Patent Nos. 7,932,241 ("the '241 patent"), 9,052,987 ("the '987 patent"), and 8,324,189 ("the '189 patent").

THE PARTIES

A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '241, '987, and '189 patents.

B. The Generic Defendants

Akorn, Inc.

4. Akorn, Inc. is a corporation organized under Louisiana law. Its principal place of business is in Lake Forest, Illinois.

5. Upon information and belief, Akorn Opthalmics, Inc. is a wholly-owned subsidiary of Akorn, Inc., a corporation organized and existing under the laws of New Jersey, having its principal place of business in Somerset, NJ. Akorn, Inc. has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal place of business in New Jersey (*i.e.*, Akorn Opthalmics, Inc.).

6. Upon information and belief, Akorn, Inc., is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

7. Upon information and belief, Akorn, Inc. submitted to the FDA ANDA No. 200918, seeking approval to market a generic version of Reclast.

8. Upon information and belief, Akorn, Inc. submitted to the FDA ANDA No. 202548 seeking approval to a market generic version of Zometa.

Strides Inc. and Agila Specialties Private Ltd.

9. Strides, Inc. is a corporation organized under New Jersey law. Its principal place of business is Lambertville, New Jersey. Strides, Inc. is a wholly owned subsidiary and agent of Strides Arcolab Ltd., an Indian company.

10. Agila Specialties Private Ltd. ("Agila") is a company organized under Indian law. Its principal place of business is in Bangalore, India. Upon information and belief, Agila is also a wholly owned subsidiary of Strides Arcolab Ltd. and is the specialties unit of Strides Arcolab Ltd.

11. Upon information and belief, Strides is the U.S. agent of Agila (collectively "Strides"). Upon information and belief, defendants Agila and Strides, Inc., are wholly owned subsidiaries of Strides Arcolab Ltd. that act in concert with respect to collaborating in the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical products. On information and belief, Strides imports, distributes, manufactures, markets, and/or sells generic versions of branded drugs in the United States, including in New Jersey.

12. Upon information and belief, Strides has submitted to the FDA ANDA No. 205254 seeking approval to market a generic version of Reclast.

USV North America, Inc.

13. USV North America, Inc. is a corporation organized under Delaware law. Its principal place of business is New York, New York.

14. Upon information and belief USV North America, Inc. is a wholly owned subsidiary and agent of USV Limited, a corporation organized and existing under the laws of India, having its principal place of business is in Mumbai, India.

15. Upon information and belief USV North America, Inc. ("USV") is in the business of, among other things, developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for distribution in the United States. Upon information and belief, USV has engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey.

16. Upon information and belief, USV has submitted to the FDA ANDA No. 202923 seeking approval to market a generic version of Zometa.

JURISDICTION AND VENUE

17. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

18. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

19. This Court has personal jurisdiction over defendants for the following reasons, among others:

a) Defendants have sold generic drugs in New Jersey, and are seeking approval and/or have obtained tentative approval to sell and/or distribute generic versions of Reclast and/or Zometa in New Jersey;

b) Novartis, which will be harmed by the defendants' actions, is domiciled in New Jersey;

c) Defendant Strides has its principal place of business in New Jersey;

d) Defendants Akorn and Strides have systematic and continuous contacts with New Jersey, in that, among other things, they sell, manufacture, import and/or distribute generic drugs in New Jersey; and

e) Defendant USV sells and/or distributes generic drugs in New Jersey.

STATEMENT OF FACTS

A. Novartis's Branded Products

20. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is approved to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

21. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4 mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003). Unopened, Zometa has a shelf life of three

years.

22. The active ingredient of Reclast is also zoledronic acid. Reclast was first approved by the FDA in 2007 and is approved to treat osteoporosis, a condition in which bones become weakened, and Paget's disease, a clinically rare genetic condition that disrupts the normal cycle of bone turnover.

23. Reclast is also administered intravenously, although the dosage of zoledronic acid in Reclast is different than Zometa. Reclast is administered as a 5 mg dose diluted in standard buffer media. Reclast is sold only in a liquid form that is fully diluted and ready to be administered. Unopened, Reclast has a shelf life of three years.

B. The Patents-In-Suit

24. The '241 patent, entitled "Pharmaceutical products comprising bisphosphonates," was duly and legally issued on April 26, 2011 and is owned by Novartis. A copy of the '241 patent is attached as Exhibit A.

25. The '987 patent, entitled "Method of administering bisphosphonates," was duly and legally issued on November 8, 2011 and is owned by Novartis. A copy of the '987 patent is attached as Exhibit B.

26. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012, and is owned by Novartis. A copy of the '189 patent is attached as Exhibit C.

27. Zometa and Reclast and their methods of use are covered by one or more claims of the '241, '987, and '189 patents, which have been listed in connection with Zometa and Reclast in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, the defendants have actual or

constructive knowledge of each of the patents.

C. The ANDA Process

28. The FDA regulates the manufacture, sale and labeling of prescription drugs in the U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an Abbreviated New Drug Application (ANDA) to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

29. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents.

30. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's Orange Book patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

31. Under 21 U.S.C. § 355(j)(2)(A)(viii), an applicant can attempt to seek a label only for uses not covered by a branded drug's method-of-use patent(s), a so-called "Section viii carve-out." If the generic drug is ultimately approved, the FDA will require the generic drug maker to duplicate only that portion of the branded drug's label not protected by the applicable method-of-

use patents, as identified in the Section viii carve-out.

D. The Generics' ANDA Applications

32. As noted above, defendants have submitted ANDAs seeking approval to manufacture and sell generic versions of Zometa and/or Reclast.

33. Defendant Akorn notified Novartis by letter that it had submitted to the FDA ANDA No. 200918 for a generic version of Reclast.

34. Defendant Akorn notified Novartis by letter that it had submitted to the FDA ANDA No. 202548 for a generic version of Zometa.

35. Defendant Strides notified Novartis by letter that it had submitted to the FDA ANDA No. 205254 for a generic version of Reclast.

36. Defendant USV notified Novartis by letter that it had submitted to the FDA ANDA No. 202923 for a generic version of Zometa.

37. With respect to ANDA Nos. 200918 and 205254, which seek approval to market a generic version of Reclast, Defendants Akorn and Strides, respectively, stated that their ANDAs included certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) with respect to the '241 patent, alleging it is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendants' generic Reclast products.

38. With respect to ANDA Nos. 202548 and 202923, which seek approval to market a generic version of Zometa, Defendants Akorn and USV, respectively, stated that their ANDAs included certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) with respect to the '189 patent, alleging it is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendants' generic Zometa products.

39. In addition, with respect to ANDA Nos. 200918 and 205254, which seek approval to market a generic version of Reclast, Defendants Akorn and Strides, respectively, have not served a Paragraph IV notice with respect to the '987 patent, but, instead, upon information and belief, have filed with the FDA a Section viii carve-out letter stating that they are only seeking approval for indications not covered by the '987 patent. Specifically, although the Reclast NDA is approved for the following uses: (1) osteoporosis, i.e., treatment and prevention of postmenopausal osteoporosis, treatment to increase bone mass in men with osteoporosis, and treatment and prevention of glucocorticoid-induced osteoporosis and (2) treatment of Paget's disease of bone in men and women, Defendants Akorn and Strides have, on information and belief, filed Section viii carve-outs stating that they are only seeking approval to market a generic version of Reclast for the treatment of Paget's disease.

40. Upon information and belief, any representation by Akorn and Strides that their proposed generic Reclast will not be offered for sale or sold for the treatment of osteoporosis is knowingly incorrect. Ninety-nine and seven-tenths percent (99.7%) of patients who take Reclast each year are being treated for conditions other than Paget's disease. Only three-tenths percent (0.3%) of patients who take Reclast do so for Paget's disease. Upon information and belief, approximately 350,000 patients are currently in treatment with Reclast. Of these 350,000 patients, only about 1,000 patients have Paget's disease.

41. Despite the relatively small size of the market for treatment of Paget's patients, no fewer than ten separate generic companies have submitted ANDAs for permission to sell Reclast. According to the U.S. Department of Health and Human Services, however, it typically costs generic drug makers $1 million to $2 million to bring a generic drug to market. Assuming these

averages hold here, Akorn and Strides would spend substantially more than the total size of the Paget's patient market in order to bring a generic Reclast product to market.

42. Doctors are free to, and frequently do, prescribe drugs for indications not identified in the drug's label. If Akorn and Strides obtain a label limited to Paget's disease, doctors can nonetheless prescribe Reclast for cancer patients or for patients suffering from osteoporosis.

43. Accordingly, upon information and belief, Akorn and Strides intend to manufacture, offer for sale and sell generic Reclast in quantities that far exceed the market for treatment of Paget's disease. Upon information and belief, Akorn and Strides do not intend that their products be used only for treatment of Paget's disease, but in fact intend for there to be substantial use of their generic Reclast products for treatment of osteoporosis.

44. This action is being commenced before expiration of forty-five days from Novartis's receipt of each of the notice letters.

COUNT I (INFRINGEMENT OF THE '241 PATENT)
(Akorn and Strides)

45. Each of the preceding paragraphs 1 to 44 is incorporated as if fully set forth herein.

46. Defendants Akorn's and Strides's generic Reclast products are covered by one or more claims of the '241 patent.

47. Defendants Akorn's and Strides's submissions of ANDA Nos. 200918 and 205254, respectively, for the purposes of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of their respective generic Reclast products before the expiration of the '241 patent are acts of infringement of the '241 patent.

48. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants Akorn's and Strides's generic Reclast products would infringe one or more claims of the '241 patent.

49. Upon information and belief, Defendants Akorn and Strides intend to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of their respective generic Reclast products immediately and imminently upon approval of Akorn's ANDA No. 200918 and Strides's ANDA No. 205254, respectively.

50. There is an actual and justiciable case or controversy between Novartis and Defendants Akorn and Strides concerning the validity and infringement of the '241 patent. Novartis is entitled to a declaration that Defendants Akorn's and Strides's commercial manufacture, use, sale, offer for sale, and/or importation of their generic Reclast drug products will infringe one or more claims of the '241 patent and that the claims of the '241 patent are not invalid.

51. Unless Defendants Akorn and Strides are enjoined from infringing the '241 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '987 PATENT)
(Akorn and Strides)

52. Each of the preceding paragraphs 1 to 51 is incorporated as if fully set forth herein.

53. The use of Defendants Akorn's and Strides' generic Reclast products to treat osteoporosis is covered by one or more claims of the '987 patent.

54. Upon information and belief, Defendants Akorn and Strides have filed "Section viii carve-outs" pursuant to Section 505(j)(A)(viii) of the FDCA, stating that they will not use the osteoporosis indication covered by the '987 patent in the labeling for their respective generic Reclast products and contending that the '987 patent does not cover Paget's disease, while they, in fact, intend to manufacture, use, offer to sell, or sell generic Reclast for the same use as claimed in the '987 patent. Accordingly, Akorn and Strides are or will be inducing infringement of the '987 patent in violation of 35 U.S.C. § 271(b), contributing to infringement in violation of 35 U.S.C. § 271(c), and, through their filing of improper or misleading ANDAs, have committed

infringement under 35 U.S.C. § 271(e)(2).

55. Upon information and belief, Defendants Akorn and Strides knew of the '987 patent when they filed their Section viii statements and know or are willfully blind to the fact that their actions have or will induce or contribute to direct infringement of the '987 patent.

56. Defendants are/will knowingly and intentionally induce infringement of the '987 patent in violation of 35 U.S.C. § 271(b). Upon information and belief, Defendants Akorn and Strides know that the vast majority of patients who are administered Reclast each year are treated for the osteoporosis indications and that only a handful of patients who are administered Reclast are treated for Paget's disease. In addition, on information and belief, Defendants Akorn and Strides have made substantial financial investments to bring their generic Reclast products to market, despite the fact that the market for the treatment of Paget's disease is so small that neither Defendants Akorn or Strides could ever hope to recoup even its initial investment costs, let alone turn a profit based on sales only to Paget's disease patients.

57. Defendants Akorn and Strides are/will also contribute to infringement of the '987 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Reclast, which is especially made for treating osteoporosis patents and which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c). Because Paget's disease patients account for only a small percentage of Reclast uses, using generic Reclast to treat Paget's disease will not be a substantial non-infringing use. Once Paget's patients (0.3% percent of the total Reclast market) are treated with zoledronic acid, treatment of osteoporosis patients, which make up the other 99.7% of the Reclast market, using generic Reclast would constitute infringing uses. Moreover, the percentage of patients who will use Defendants Akorn's and Strides's generic Reclast products to treat Paget's disease is even

smaller than that already insubstantial number, insofar as the already small sliver of the market will be further divided among at least ten generic manufacturers. In addition, many Paget's patients will require only a single dose and be cured, and even those who experience relapse will require infrequent treatment.

58. Upon information and belief, Defendants Akorn's and Strides's filing of a so-called "Section viii carve-out" pursuant to Section 505(j)(A)(viii) of the FDCA were shams given their intent to manufacture and sell generic Reclast for the osteoporosis indications. Upon information and belief, Defendants Akorn's and Strides's submissions to the FDA are misleading because they represent that Defendants Akorn and Strides intend to sell generic Reclast only to treat Paget's disease, and do not disclose Defendants Akorn's and Strides's true intent that generic Reclast be sold and used almost exclusively to treat osteoporosis.

59. There is an actual and justiciable case or controversy between Novartis and Defendants Akorn and Strides concerning the validity and infringement of the '987 patent. Novartis is entitled to a declaration that Defendants Akorn's and Strides's manufacture, use, sale, offer for sale, and/or importation of their generic Reclast products will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '987 patent, and that the claims of the '987 patent are not invalid.

60. Unless Defendants Akorn and Strides are enjoined from infringing the '987 patent, actively inducing infringement of the '987 patent, and/or contributing to the infringement by others of the '987 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT III (INFRINGEMENT OF THE '189 PATENT)
(Akorn and USV)

61. Each of the preceding paragraphs 1 to 60 is incorporated as if fully set forth herein.

62. The use of Defendants Akorn and USV's generic Zometa products is covered by one or more claims of the '189 patent.

63. Upon information and belief, Defendants Akorn and USV knew of the '189 patent when they submitted ANDA Nos. 202548 and 202923, respectively, and know or are willfully blind to the fact that their actions will induce or contribute to direct infringement of the '189 patent.

64. Defendants Akorn and USV's submissions of ANDA Nos. 202548 and 202923, respectively, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of their Zometa products before the expiration of the '189 patent are acts of infringement of the '189 patent under 35 U.S.C. § 271(e)(2).

65. Use of Defendants Akorn's and USV's generic Zometa products in accordance with and as directed by Defendants Akorn's and USV's proposed labeling for those products would infringe or more claims of the '189 patent.

66. Upon information and belief, Defendants Akorn and USV intend to engage in the manufacture, use, offer for sale, sale, and/or importation of their respective generic Zometa products with their proposed labeling immediately and imminently upon approval of their respective ANDAs.

67. Upon information and belief, Defendants Akorn and USV will actively induce infringement of the '189 patent in violation of 35 U.S.C. § 271(b) when their ANDAs are approved, and plan and intend to, and will do so immediately and imminently upon approval.

68. Upon information and belief, Defendants Akorn and USV know that their generic

Zometa products and their proposed labeling are especially made or adapted for use in infringing the '189 patent, and that their generic Zometa products and their respective proposed labeling are not suitable for substantial noninfringing use.

69. Upon information and belief, Defendants Akorn and USV plan and intend to, and will, contribute to the infringement of the '189 patent immediately and imminently upon approval of their respective generic Zometa products in violation of 35 U.S.C. § 271(c).

70. There is an actual and justiciable case or controversy between Novartis and Defendants Akorn and USV concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendants Akorn's and USV's manufacture, use, sale, offer for sale, and/or importation of their generic Zometa drug products will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are not invalid.

71. Unless Defendants Akorn and USV are enjoined from infringing the '189 patent, actively inducing infringement of the '189 patent, and/or contributing to the infringement by others of the '189 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against defendants as follows:

1. Declaring that the '241, '987, and '189 patents are not invalid;

2. Declaring that the defendants have infringed, directly or indirectly, one or more claims of the '241, '987, and '189 patents;

3. Damages or other monetary relief to Novartis if defendants engage or continue to engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of generic versions of Reclast or Zometa prior to the latest expiration date of the '241, '987, and/or '189 patents, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that the defendants engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Reclast or Zometa have willfully infringed the claims of the '241, '987, and/or '189 patents;

5. An order permanently enjoining Defendants, and their affiliates, subsidiaries, officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic versions of Zometa and Reclast until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled; and

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: August 26, 2013

s/ William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Attorneys for Novartis Pharmaceuticals Corporation

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey.

Dated: August 26, 2013

Respectfully Submitted,

s/William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street

Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Attorneys for Novartis Pharmaceuticals Corporation